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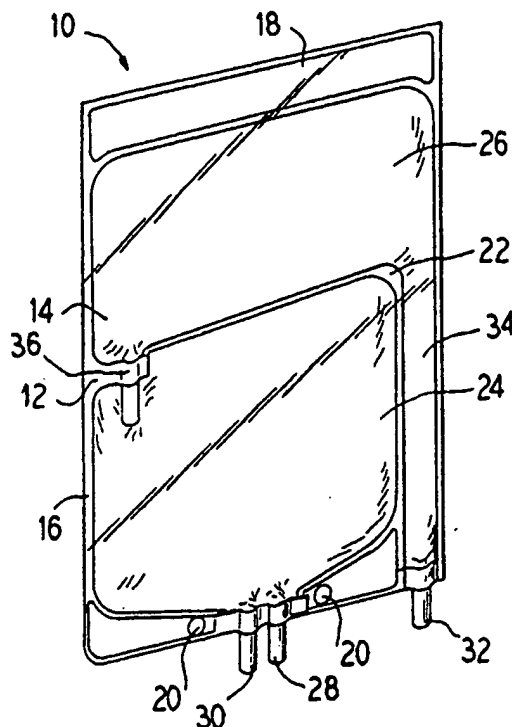
INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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<p>(21) International Application Number: PCT/US94/00546 (22) International Filing Date: 18 January 1994 (18.01.94) (30) Priority Data: 08/006,339 19 January 1993 (19.01.93) US (71) Applicant: BAXTER INTERNATIONAL INC. [US/US]; One Baxter Parkway, Deerfield, IL 60015 (US). (72) Inventors: BALTEAU, Patrick; 33/014, rue Van-Opre, B-5100 Jambes (BE). FAICT, Dirk; Gravenstraat 1, B-9968 Assenede (BE). PELUSO, Francesco; Verbindingslaan 70, B-3001 Heverlee (BE). (74) Agents: BORECKI, Thomas, S. et al.; 1620 North Waukegan Road, McGaw Park, IL 60085 (US).</p>		<p>(81) Designated States: AU, CA, JP, KR, NZ, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Published With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</p>

(54) Title: MULTIPLE CHAMBER CONTAINER

(57) Abstract

A multiple chamber container (10) for mixing and administering a plurality of products. The container (10) has at least two chambers (24, 26) separated by a seal line (22). A frangible connector (36) is situated between the two chambers (24, 26) for mixing the products contained within the chambers as desired. Each chamber (24, 26) has at least one port (28, 32) for filling of product into the chamber. The ports (28, 32) are located on the same exterior side of the container such that the chambers can be filled without folding the bag and by using existing filling equipment.



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S P E C I F I C A T I O N
"MULTIPLE CHAMBER CONTAINER"
BACKGROUND OF THE INVENTION

5 The present invention generally relates to a multiple chamber container. More specifically, the invention relates to a flexible bag for storing a medical product having two or more chambers each containing a solution or other product.

10 It is known to house a number of different products in flexible containers. For example, in the medical field, it is known to house enteral, intravenous, and peritoneal solutions in flexible containers. Generally, medical solutions can be administered directly to a patient through a port that provides fluid communication
15 to an interior of the container.

 Often, one or more solutions or ingredients are combined to form a solution to be administered to the patient. Combined medical solutions may be typically unstable. Degradation of mixed solutions can occur
20 during the manufacturing process, for example during sterilization. Likewise during long term storage such products may degrade or suffer reduced efficacy. For example, amino acid and dextrose may be combined to form a parenteral solution for intravenous administration to
25 a patient. If amino acid and dextrose are combined in a single container and stored, discoloration often takes place. Other examples of non-compatible solutions include: bicarbonate-dextrose; amino acid polymers-dextrose; bicarbonate-dextrose polymers; and amino acid
30 polymers-dextrose polymers.

 As a result, in some situations, amino acids and dextrose are sold separately. If a combined amino acid and dextrose solution is prescribed, the amino acid solution and dextrose solution must be combined from two
35 separate containers. The transfer of fluid from one

container to another can be time consuming and requires the use of transfer tubing and/or connectors between the two separate containers. Additional risks for fluid contamination is also present using such procedures.

5 Containers, therefore, have been developed to reduce the risk of contamination and to provide a more simple and less time consuming procedure for combining at least two solutions. For example, containers having more than one chamber for storing a respective number of
10 solutions prior to mixing are known. The chambers of these containers are segregated from each other, but selective communication is possible through the use of a frangible seal or closure between the chambers which may be opened from outside the container by manipulating
15 the walls of the container.

An example of such a container is set forth in U.S. Patent No. 4,465,488 to Richmond et al. As disclosed in the '488 patent, an interior of a flexible, plastic container is separated into two chambers by a heat seal.
20 A connecting port between the two chambers is sealed by a frangible seal. When the seal is broken, the two chambers are in fluid communication through the port.

Another multiple chamber container is described in U. S. Patent No. 4,396,383 to Hart. As described in the
25 disclosure of Hart, a container having a two-chamber construction provides for passive mixing of two solutions having different specific gravities into a single homogenous solution in a closed environment. The container includes fill ports at opposite ends of the
30 container for filling the respective chambers with solutions. The chambers, however, may not be filled simultaneously without folding the bag or without specially designed filling equipment which can fill the chambers from opposite sides.

A need, therefore, exists for an improved multiple chamber container.

SUMMARY OF THE INVENTION

The present invention provides an improved multiple
5 chamber container for housing and dispensing a plurality
of products. The container is constructed such that the
products may be filled and stored in two separate
chambers within the container. A frangible valve between
the chambers, when broken, allows the products in the two
10 chambers to be mixed to form a single solution that can
be dispensed and administered to a patient. The ports to
the chambers are located on the same exterior side of the
container such that the chambers may be filled
simultaneously without folding the bag and by using
15 currently available filling equipment.

In an embodiment, the present invention provides
a container for mixing two products. The container
includes on an interior thereof dividing means that
define a first chamber and a second chamber. The first
20 chamber may be filled with a first product and the second
chamber may be filled with a second product. A frangible
valve between the chambers provides selective
communication between the chambers. A first port
connected to the first chamber on one of the exterior
25 sides of the container can be used for filling the first
chamber. A second port connected to the second chamber
is located on the same exterior side of the container as
the first port for filling the second chamber.

In an embodiment, the first port and the second
30 port are on the exterior side at the base of the
container.

In an embodiment, the first and the second port are
on the exterior side at the top of the container.

In an embodiment, an additional port is provided for providing means for adding additional product to the chambers or for dispensing product from the chambers.

5 The present invention also provides a method for filling and mixing products in a container. The method comprises the steps of filling a first chamber with a first solution through a first port and filling a second chamber with a second solution through a second port. The first port and the second port are located on the
10 same exterior side of the container.

In an embodiment, the method further comprises the step of breaking a frangible connector between the first chamber and the second chamber and mixing the products contained within the chambers.

15 Although the present invention can be used to store any variety of products, the container is especially adaptable for storing medical solutions, especially peritoneal dialysis solutions.

20 An advantage of the present invention is that it provides a container for filling and mixing two or more products without folding the container.

A further advantage of the present invention is that it provides a method for filling and mixing two or more products without specially designed filling
25 equipment.

Furthermore, an advantage of the present invention is that it provides a container for filling and mixing two or more products prior to administration of the mixed products to a patient.

30 Moreover, an advantage of the present invention is that it provides a container for filling and mixing two or more products without product degradation.

Additional features and advantages of the present invention are described in, and will be apparent from,

the detailed description of the presently preferred embodiments and from the drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

5 Figure 1 illustrates a perspective view of an embodiment of a multiple chamber container of the present invention.

Figure 2 illustrates a front elevational view of the embodiment of the multiple chamber container shown in Figure 1.

10 Figure 3 illustrates a cross-sectional view of a portion of the multiple chamber container taken generally along the lines III-III in Figure 2.

15 Figure 4 illustrates a front elevational view of another embodiment of a multiple chamber container of the present invention.

Figure 5 illustrates a cross-sectional view of the multiple chamber container taken generally along the lines V-V in Figure 4.

DETAILED DESCRIPTION OF THE

PRESENTLY PREFERRED EMBODIMENTS

20 In accordance with the present invention, a multiple chamber container 10 is provided for housing and mixing at least two solutions or products into a single mixture prior to administration to a patient.

25 Referring to Figures 1-3, wherein like numerals designate like components, a container 10 constructed pursuant to the present invention is illustrated. The container 10 is defined, at least in part, by walls 12 and 14. Container walls 12 and 14 may be formed from flexible plastic sheets joined by means such as a heat seal 16 about the periphery of the walls 12 and 14. If
30 desired, however, the walls 12 and 14 can be formed from a single web of film that is folded and sealed along three sides to create the container 10.

In the illustrated embodiment, a wider portion of the heat seal 16 is formed at an end of the container 10 to form a flange 18. The flange 18 generally can have a stronger heat seal to assist the container 10 in keeping its shape when suspended.

Likewise, in the illustrated embodiment, openings 20 are provided within the heat seal 16 at the lower end of the container 10. The openings 20 provide means for hanging the container 10 and holding the container 10 in a stable position during the filling process.

The interior of the container is divided by a heat seal 22 into a lower chamber 24 and an upper chamber 26. The seal 22 and the walls 12 and 14 of the container 10 define the boundaries of the lower chamber 24 and the upper chamber 26.

A fill port 28 is located at the lower end of the lower chamber 24 to provide a means for adding product to the chamber 24. In addition, in the illustrated embodiment, a medication port 30 is located adjacent the fill port 28 of the lower chamber 24. It should be appreciated that although a medication port 30 is provided, the container 10 can be constructed without the port or with additional ports.

A second fill port 32 is located at the lower end of the container 10 at the lower end of the upper chamber 26. In this regard, the upper chamber 26 includes a channel 34 which provides communication between the fill port 32 and the upper chamber 26.

In order to provide means for allowing the fluid contained within the lower and upper chambers 24 and 26 to be mixed, a frangible connector 36 is provided. The frangible connector 36 is located between the lower chamber 24 and the upper chamber 26 to provide communication between the chambers 24 and 26. When the frangible connector 36 is broken by a user, such as

medical personnel, fluid communication is established between the two chambers. A number of possible frangible connector structures can be used. U.S. Patent No. 4,465,488, the disclosure of which is incorporated herein by reference, discloses one such possible structure.

The container 10 may, therefore, be constructed such that the seal 22 defines a top portion of the lower chamber 24 which substantially meets with a lower portion of the upper chamber 26. The seal 22 further extends perpendicularly to the side of the container along a side of the lower chamber 24 and the fluid channel 34 of the upper chamber 26.

To mix the solutions of the chambers 24 and 26, the frangible connector 36 situated between the chambers 24 and 26 is manipulated until the frangible connector 36 is selectively opened by the user who forcibly breaks the frangible connector 36. Fluid communication between the chambers will then be established.

In the preferred embodiment illustrated, the frangible connector 36 is situated between the top portion of the lower chamber 24 and the lower portion of the upper chamber 26. The frangible connector 36, as illustrated in Figure 2, includes at least one tube 38 with a break away valve 40 therein. The break away valve 40 may be mounted within the plastic tube 38 as is well known to provide communication between products in the chambers 24 and 26. However, other constructions of valves within the tube 38 of the frangible connector 36 may also be implemented in the container 10 of the present invention.

To mix the solution within the chambers 24 and 26, the frangible connector 36 is broken. The transfer of product is thereby initiated from the upper chamber 26 to the lower chamber 24. Typically, a higher specific gravity solution is stored in the upper chamber 26 than

the solution stored in the lower chamber 24. However, one of the chambers may include a "dry" product for mixing with a solution. Upon breaking of the frangible connector 36, the heavier solution from the upper chamber 26 flows into the lower chamber 24 through the valve 40 of the frangible connector 36 with the container 10 suspended such that the chamber 26 is substantially above the chamber 24.

As a result, the solution level in the upper chamber 26 decreases as the product level in the lower chamber 24 increases. Once the product from the upper chamber 26 is depleted therefrom and added to the lower chamber 24, the mixed solution can be dispensed through the port 28.

The illustrated embodiment of Figures 1 and 2 illustrates three ports. Two ports 28 and 30 may be connected to the lower chamber 24, and a single port 32 is connected to the channel 34 of the upper chamber 26. The additional port 30 connected to the lower chamber 24 may be used as a port for addition of further product or solution or as a supplemental administration port.

When mixing of products has been completed, a mixture of the two solutions is located in the lower chamber 24. Typically, the volume ratio between the lower chamber 24 and the upper chamber 26 is at least $2/3$.

An alternative embodiment of a multiple chamber container 50 is illustrated in Figures 4 and 5. The container 50 is generally illustrated in Figure 4. The container 50 includes two outer walls 52 and 54 which are sealed together by a heat seal 56 about the periphery of the walls 52 and 54. The internal seal 58 divides the interior of the container 50 into a lower chamber 60 and an upper chamber 62.

The lower chamber 60 may include three ports 64, 66, and 68 in fluid communication with the lower chamber 60 as illustrated. While three ports are shown connected to the lower chamber 60, it should be understood that
5 only two ports would be required for filling and administering a mixed solution from the container 50.

The upper chamber 62 includes a single port 70. The port 68 provides a means for filling the lower chamber 60, and the port 70 acts as a filling port for
10 the upper chamber 62. The ports 68 and 70 may be located adjacent a flange 72 which is formed by a wider area of the walls 52 and 54 being heat sealed at the top portion of the container 50.

A frangible connector 74 is situated between a top
15 portion of the lower chamber 60 and a bottom portion of the upper chamber 62. When the frangible connector 74 is broken, a valve 76 located within a plastic tube 78 of the frangible connector 74 allows fluid communication between the chambers 60 and 62.

Using the embodiment illustrated in Figures 4 and
20 5 for filling, mixing and administering one or more products to a patient, an additional port is provided than that described with reference to Figures 1-3 since both a fill port 68 and a drainage port 66 are provided
25 for the lower chamber 60. The medication port 64 may optionally be included as desired for further addition of medication or supplemental administration.

In an embodiment of the present invention, the frangible seal is eccentric, i.e., located at one side.
30 This provides, in some cases, improved mixing.

The containers 10 and 50 of the present invention are especially adapted for use in storing peritoneal dialysis solutions. A peritoneal dialysis solution usually includes as an osmotic agent dextrose or a
35 similar compound. Similar to other medical solutions,

it is known to sterilize peritoneal dialysis solutions with heat. Dextrose must be formulated at an acid pH (5-5.5) since dextrose caramelizes during sterilization at high pH.

5 However, it is desirable to maintain the other components of a peritoneal dialysis solution at a high pH. Thus, when the two solutions are mixed they are at a physiological pH. Therefore, it is known to store in two separate bags a peritoneal dialysis solution that is
10 mixed when administered to the patient.

 Pursuant to the present invention, the dextrose solution having a low pH can be filled in one of the chambers of the container 10 or 50. The other chamber can include the base portion of the peritoneal dialysis
15 solution. The solutions can then be sterilized using heat. Following the post-sterilization, the two solutions can be mixed into the lower chamber of the container thereby raising the pH of the dextrose solution to a physiological acceptable pH of 6.5 to 7.4.

20 Accordingly, pursuant to the present invention, the dextrose formulation can be stored and sterilized at a low pH preventing caramelization. However, before being administered to the patient, the pH of the formulation can be brought to a physiological acceptable pH thereby
25 reducing pain on infusion as well as reducing inhibition of polymorph phagocytosis and intracellular killing of bacteria.

 By way of example, and not limitation, an example of a process for storing and sterilizing a peritoneal
30 dialysis solution is as follows. The dextrose solution and base solution of a peritoneal dialysis solution are prepared separately. Electrolytes are distributed into the two separate solutions to achieve the best pH distribution. The dextrose and base solutions are placed

in different compartments of the containers using the fill ports.

5 The container can now be sterilized without caramelization of the dextrose. After sterilization and prior to use, the connector is broken allowing mixing of the solutions.

10 It should be understood that various changes and modifications to the presently preferred embodiments described herein will be apparent to those skilled in the art. Such changes and modifications may be made without departing from the spirit and scope of the present invention and without diminishing its attendant advantages. It is, therefore, intended that such changes and modifications be covered by the appended claims.

WE CLAIM:

1. A container for housing two products comprising:

a container defining an interior;

5 means for dividing the interior into a first chamber and second chamber;

a valve for providing selective communication between the first chamber and the second chamber;

10 a first port in fluid communication with the first chamber on one exterior side of the container; and

a second port in fluid communication with the second chamber on the same exterior side of the container as the first port.

15 2. The container of claim 1 wherein the valve includes a frangible member.

3. The container of claim 1 wherein the exterior side including the first port and the second port is at its base.

20 4. The container of claim 1 wherein the exterior side including the first port and the second port is at its top end.

5. The container of claim 1 wherein the second port may dispense the mixed solutions.

25 6. The container of claim 1 further comprising a third port in fluid communication with one of the chambers.

7. The container of claim 1 wherein the second chamber has a larger volume than the first chamber.

30 8. A container for filling and storing two products prior to mixing the products into a mixture comprising:

a first chamber for holding a first product that enters the first chamber through a first port;

35 a second chamber for holding a second product that enters the chamber through a second port; and

the first port and the second port being located at the same exterior side of the container.

9. The container of claim 8 further comprising a container dividing seal between the first chamber and the second chamber.

10. The container of claim 8 further comprising a frangible connector between the first chamber and the second chamber.

11. The container of claim 8 further comprising an additional port in fluid communication with at least one of the chambers.

12. The container of claim 8 wherein the first port and the second port are at the exterior side of the container wall at its base.

13. The container of claim 8 wherein the frangible connector is eccentric.

14. A method for filling and mixing products in a container comprising the steps of:

filling a first chamber with a first product through a first port; and

filling a second chamber with a second product through a second port wherein the first port and the second port are located on the same exterior side of the container.

15. The method of claim 14 further comprising the step of breaking a frangible connector between the first chamber and the second chamber.

16. The method of claim 15 further comprising the steps of mixing the first product and the second product forming a solution and administering the mixed solution from one of the chambers.

17. The method of claim 16 wherein the administration of the mixed solution is through one of the ports.

18. The method of claim 14 further comprising the step of adding additional product to one of the chambers through a third port.

5 19. A method for housing a peritoneal dialysis solution comprising the steps of:

filling a first chamber of a container having at least two chambers with a dextrose solution through a fill port located on a first side of the container; and

10 filling a second chamber of the container with a base solution through a second fill port located on the first side of the container.

20. The method of Claim 19 including the step of heat sterilizing the container and the dextrose and base solutions.

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FIG. 1

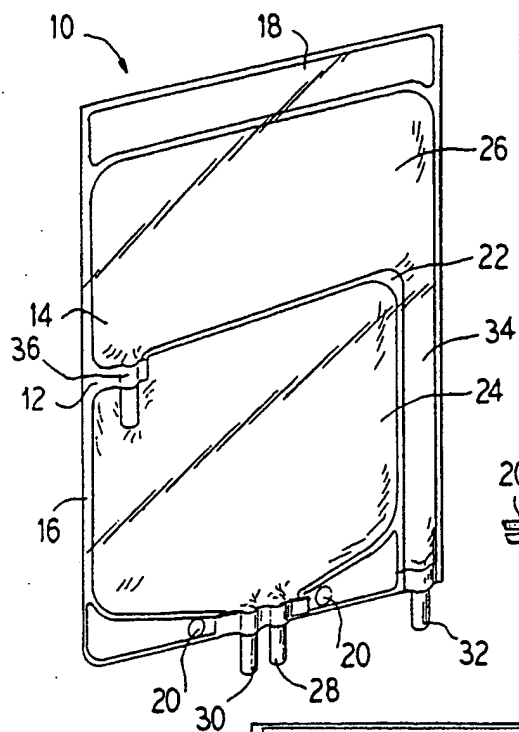


FIG. 3

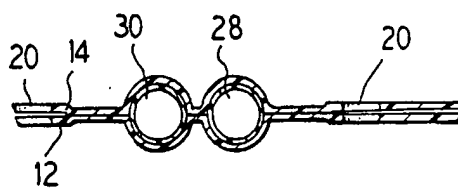
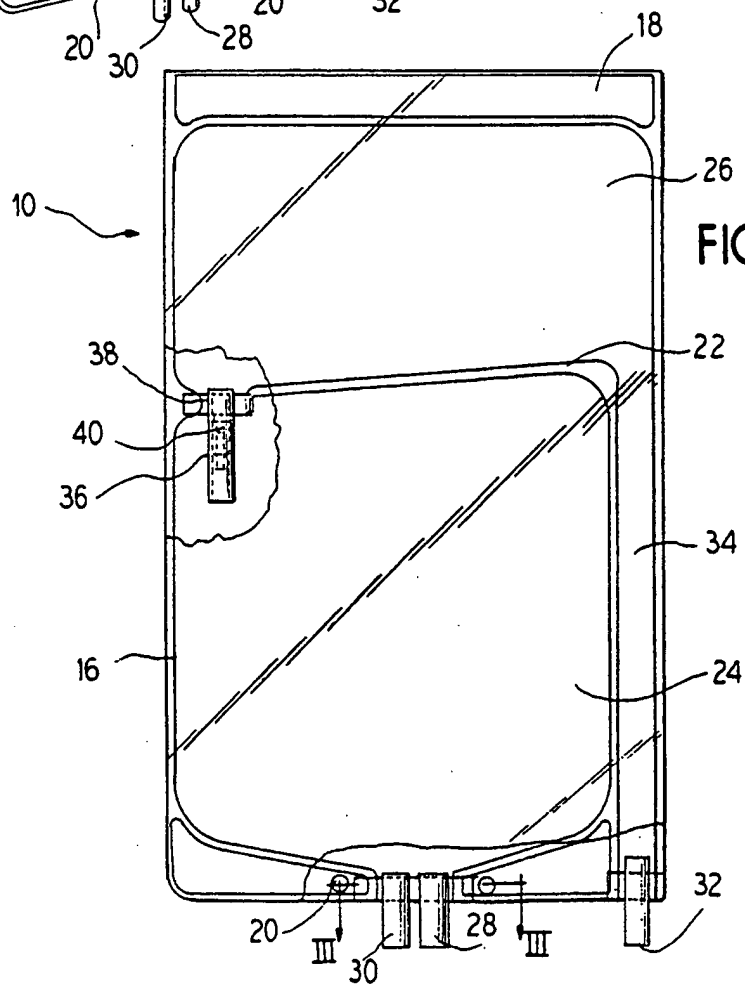


FIG. 2



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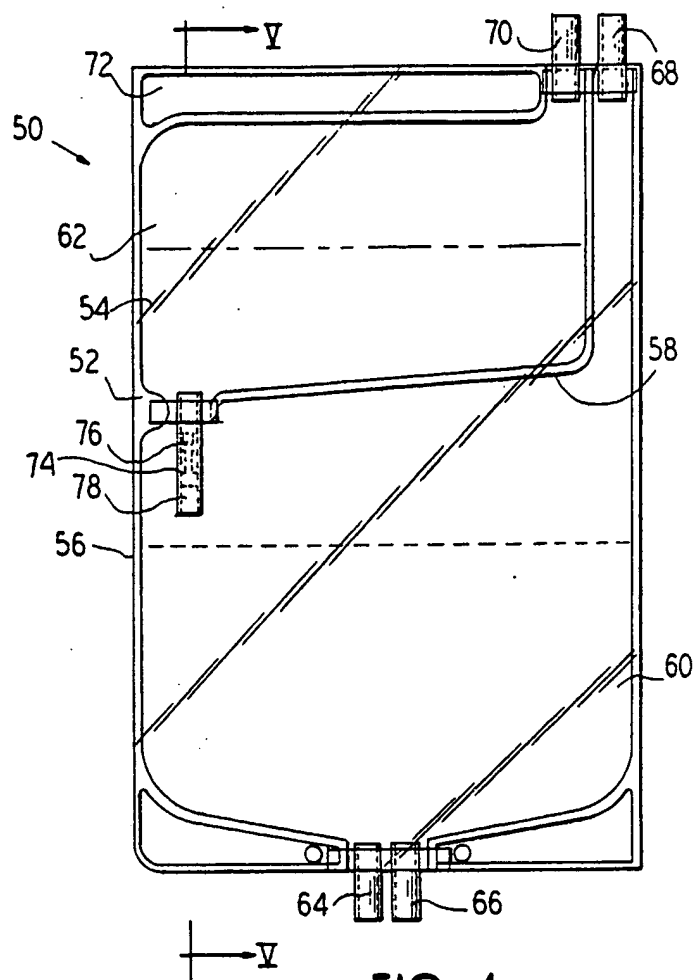


FIG. 4

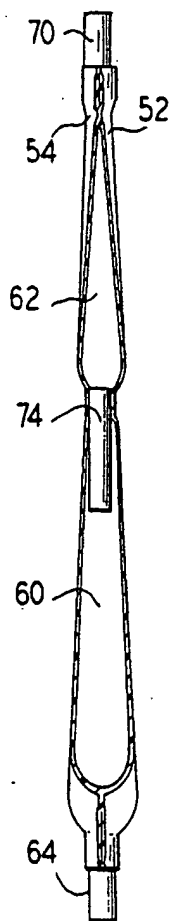


FIG. 5

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 94/00546

A. CLASSIFICATION OF SUBJECT MATTER IPC 5 A61J1/00		
According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED		
Minimum documentation searched (classification system followed by classification symbols) IPC 5 A61J		
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Electronic data base consulted during the international search (name of data base and, where practical, search terms used)		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US,A,4 608 043 (LARKIN) 26 August 1986 see column 1, line 10 - line 13 see column 1, line 34 - line 39 see column 2, line 47; figures ---	1-3,5, 8-10, 12-17, 19,20
X	DE,A,32 38 649 (THEUER) 19 April 1984 see claim 1; figures 1,5 --- -/--	1-6, 8-12, 14-20
<input checked="" type="checkbox"/> Further documents are listed in the continuation of box C. <input checked="" type="checkbox"/> Patent family members are listed in annex.		
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Date of the actual completion of the international search 27 April 1994		Date of mailing of the international search report 25.05.94
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INTERNATIONAL SEARCH REPORT

International application No.
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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US,A,4 465 488 (RICHMOND ET AL.) 14 August 1984 cited in the application see column 5, line 19 - line 23; figures 1,11 -----	1,2, 6-11, 14-16, 19,20
A	US,A,4 396 383 (HART) 2 August 1983 cited in the application see figure 1 -----	13

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/US 94/00546

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US-A-4608043	26-08-86	NONE	
DE-A-3238649	19-04-84	NONE	
US-A-4465488	14-08-84	NONE	
US-A-4396383	02-08-83	AU-A- 9122982	18-05-83
		CA-A- 1209957	19-08-86
		EP-A, B 0093148	09-11-83
		WO-A- 8301569	11-05-83